

REMARKS

Claims 1, 7-14, 16-27, 29-38, and 40-45 are pending in the application. Claims 24-27, 29-38, and 40 are withdrawn. Claims 1, 7, 20-23, and 42-45 have been amended. Support for the amendments to the claims can be found throughout the specification and claims as filed. No new matter has been added.

Amendment or cancellation of claims should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. Amendments or cancellations have been made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the option to prosecute the originally filed claims further, or similar ones, in the instant or subsequently filed patent applications.

Restriction Requirement and Drawings

In response to the Examiner's indication that only claims 1, 7-10, 16, 18, 20, and 22 have been examined on the merits, Applicants respectfully submit that the Group I invention encompassing claims 1, 7-14, 16-23, and 41-45 was elected in the Response to Restriction Requirement filed on November 22, 2010. Applicants therefore respectfully request rejoinder of claims 11-14, 17, 19, 21, 23, and 41-45 for examination on the merits.

Applicants further gratefully acknowledge the Examiner's withdrawal of the species election of Group A upon further consideration of Applicant's Response to Restriction Requirement filed on November 22, 2010, as well as the Examiner's indication that the drawings filed on November 7, 2005 have been accepted.

Rejection of Claims 1, 7-10, 16, 18, 20, and 22 Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 7-10, 16, 18, 20, and 22 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite on a number of grounds. In response, Applicants have amended claim 1 to no longer recite GenBank Accession # Z95324 A1 123456 and to provide antecedent basis for the recitation of "(i)" to correct grammatical errors. In an effort to expedite prosecution and in no way conceding to the rejection, Applicants have also amended the preambles of claims 20 and 22, as well as claims 21, 23, and 42-45, to no longer recite "enhancing." Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 1, 7-9, 16, 20, and 22 Under 35 U.S.C. § 102(b)

Claims 1, 7-9, 16, 20, and 22 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wu and Hung (WO 01/29233). Specifically, the Examiner is of the opinion that “[a]n example of the nucleic acid encoding fusion protein taught by Wu and Hung includes a signal sequence; a full-length heat shock protein 70 or the carboxy terminus thereof, such as that of SEQ ID NO: 9; and a HPV E7 protein from HPV-16” (see page 4 of the pending Non-Final Office Action).

Applicants respectfully traverse the rejection. In order to anticipate a claimed invention under 35 U.S.C. § 102(b), a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation. *Impax Labs., Inc. v. Aventis Pharmaceuticals Inc.*, No. 07-1513 (Fed. Cir. Oct. 3, 2008). The factors to be considered when determining whether the experimentation required to practice an invention is undue include the quantity of experimentation; the amount of direction or guidance present; the presence or absence of working examples; and the predictability or unpredictability of the art. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

In pages of 2, 3, 7, 14, 26, and 34 cited by the Examiner at page 4 of the pending Non-Final Office Action, The cited Wu and Hung document discloses a number of chimeric polypeptides “comprising a carboxy terminal fragment of a heat shock protein (HSP), an Flt-3 ligand (FL), a cytoplasmic translocation domain of a *Pseudomonas* exotoxin A (ETA dII), or a granulocyte-macrophage-colony stimulating factor (GM-CSF) sequence, and a second polypeptide domain comprising an antigenic polypeptide” (see page 1, line 29 to page 2, line 3). Wu and Hung further teaches that such chimeric polypeptides “can also include additional sequence, *e.g.*, linkers, epitope tags, enzyme cleavage recognition sequences, signal sequences, secretion signals, and the like” (see page 26, lines 14-17). Thus, Wu and Hung discloses a practically unlimited number of fusion protein sequences to use in combination with a variety of immune stimulating and antigenic polypeptides.

Thus, as in *Impax Labs, supra*, the alleged prior art document discloses a particularly large number of possible therapeutic agents in the absence of any guidance or working examples that would provide a skilled artisan with a rational underpinning for producing the presently claimed subject matter without undue experimentation and without impermissible hindsight bias

based upon the teachings of Applicant's specification. Therefore, Applicants respectfully submit that Wu and Hung does not qualify as a valid reference under 35 U.S.C. § 102(b) and respectfully request withdrawal of the rejection.

Rejection of Claims 10 and 18 Under 35 U.S.C. § 103(a)

Claim 18 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wu and Hung (WO 01/29233), as applied to claims 1, 7-9, 16, 20, and 22, and further in view of Konishi *et al.* (Virology (2000) 268:49-55). Specifically, the Examiner is of the opinion that "[t]he teachings of Wu and Hung are discussed above, however, they do not teach the use of the plasmid PNGVL4a as their expression vector. Konishi *et al.* teach the use of pNGVL4a in designing an expression vector for in vivo use" (see page 5 of the pending Non-Final Office Action).

Applicants respectfully traverse the rejection. Applicants have established above that Wu and Hung does not teach each and every element of claims 1, 7-9, 16, 20, and 22. Applicants respectfully submit that Konishi *et al.* does not remedy the deficiencies of Wu and Hung, at least because it only teaches the use of the plasmid PNGVL4a. Since claim 18 depends from claims 1 and 16, Applicants respectfully submit that neither the Wu and Hung nor Konishi *et al.*, either alone or in combination, teaches each and every element of rejected claim 18. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 10 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wu and Hung (WO 01/29233), as applied to claims 1, 7-9, 16, 20, and 22, and further in view of Edmonds and Vousden (J. Virol. (1989) 63:2650-2656). Specifically, the Examiner is of the opinion that "[t]he teachings of Wu and Hung are discussed above, however, they do not teach an amino acid change to the E7 protein. Edmonds and Vousden teach the mutation of the E7 protein from HPV-16 by changing the 24 amino acid from a Cysteine to a Glycine" (see page 6 of the pending Non-Final Office Action).

Applicants respectfully traverse the rejection. Applicants have established above that Wu and Hung does not teach each and every element of claims 1, 7-9, 16, 20, and 22. Applicants respectfully submit that Edmonds and Vousden does not remedy the deficiencies of Wu and Hung, at least because it only teaches the cysteine-to-glycine mutation of HPV-16-E7 protein at

residue 24. Since claim 10 depends from claims 1 and 7-9, Applicants respectfully submit that neither the Wu and Hung nor Edmonds and Vousden, either alone or in combination, teaches each and every element of rejected claim 10. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Early and favorable consideration of the application is respectfully solicited. If a telephone conversation with Applicant's attorney would expedite prosecution of the above-identified application, the Examiner is invited to call the undersigned at (617) 832-1000. Please charge any additional fees required to enter this response, or credit any overpayment, to **Deposit Account No. 06-1448, Reference JHV-050.01.**

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Respectfully submitted,

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